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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,884	02/06/2007	Patrick Joseph Caroline	7605P001	6793
8791 7590 7790 7790 7790 7790 7790 7790 7790			EXAMINER	
			GREECE, JAMES R	
			ART UNIT	PAPER NUMBER
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			07/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Application No. Applicant(s) 10/551,884 CAROLINE ET AL. Office Action Summary Examiner Art Unit JAMES R. GREECE 2873 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 06 February 2007. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-5 and 7-15 is/are pending in the application. 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration. 5) Claim(s) 1-5 and 7-11 is/are allowed. 6) Claim(s) 12-14 is/are rejected. 7) Claim(s) 15 is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) ☑ The drawing(s) filed on 30 September 2005 is/are: a) ☑ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date. Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Notice of Informal Patent Application Paper No(s)/Mail Date 5/9/2008 6) Other:

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#### Detailed Action

Applicant cooperation is requested in correcting any errors of which applicant may become aware in the specification.

### Status of the Application

Claims 1-5 and 7-15 are pending in this application

### Claim Rejections - 35 USC § 102

 Claims 12-14 are rejected under 35 U.S.C. 102(a, e) as being anticipated by Mitsui (USPUB 2003/0095232 of record).

In regard to claim 12, Mitsui teaches:

determining the required refractive correction for the eye; (see paragraph 0088-0089) characterizing the surface shape of at least that part of the eye which is to be subjected to reshaping; (See paragraph 0087) and selecting a soft lens formed of a material and having a geometric configuration such that when fitted to the eye will apply pressures to the surface of the eye in such manner as to assist in the required corneal reshaping (See paragraph 0091).

In regard to claim 13, Mitsui teaches:

Wherein said selection process involves a modeling process adapted to predict anticipated pressures and different zones of the wearer's eye (See paragraph 0076)

In regard to claim 14, Mitsui teaches:

Said modeling process is a finite element modeling process (0091-0092)

## Allowable Subject Matter

2. Claims 1-5 and 7-11 are allowed.

The following is a statement of reasons for the indication of allowable subject matter: The prior art taken singularly or in combination fails to anticipate or fairly suggest the limitations of the independent claims, in such a manner that a rejection under 35 U.S.C. 102 or 103 would be proper.

In regard to independent claim 1, the prior art taken either singly or in combination fails to anticipate or fairly suggest an orthokeratology lens formed of a homogenous material having an elastic modulus between .2 and 10 MPa; specifically recited together in combination with the totality of particular features/limitations recited therein.

# Claim Objections

 Claim 15 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

The prior art taken singularly or in combination fails to anticipate or fairly suggest the limitations of the independent claims, in such a manner that a rejection under 35 U.S.C. 102 or 103 would be proper.

In regard to dependent claim 15, the prior art taken either singly or in combination fails to anticipate or fairly suggest an orthokeratology method including a contact lens that is manufactured to have a natural orientation and an everted orientation and is functional in both orientations and stable when placed on the eye; specifically recited together in combination with the totality of particular features/limitations recited therein.

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### Response to Arguments

- 4. Applicant's arguments filed 4/4/2008 regarding claims 12-14 have been fully considered but they are not persuasive. The Mitsui reference refers to utilizing soft contact lenses in at least example 1, therefore the argument applied by the applicant to disprove the rejection of the examiner is not persuasive as the reference discloses utilizing a soft contact lens to assist in the process of corneal reshaping. As the claim does not indicate the soft contact lens to specifically cause the reshaping there are a number of ways in which the soft contact lens pressures on the cornea can provide assistance in the corneal reshaping process. Therefore the examiner has applied the broadest reasonable interpretation to these limitations that constitute the 6-8th lines of claim 12. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26

  USPQ2d 1057 (Fed. Cir. 1993). For the applicant to overcome the 102 rejection as previously presented, the applicant must differentiate from the teachings of Mitsui, in their claim language.
- 5. Further the prior art's teaching is not overcome by the testimony of the expert in the field as there is no manner in which to quantify the expert's remarks, that is there is no explicit definition of what a rigid contact lens is, what level of elastic modulus constitutes a rigid contact lens, and is a rigid contact lens necessarily a hard contact lens.

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### Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES R. GREECE whose telephone number is (571)272-3711. The examiner can normally be reached on M-Th 7:30-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ricky Mack can be reached on 571-272-2333. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/David N. Spector/

Primary Examiner, Art Unit 2873

/J. R. G./ James R Greece Examiner, Art Unit 2873 6/23/2008